**UNITED STATES DISTRICT COURT**

**NORTHERN DISTRICT OF CALIFORNIA**

**ELIZABETH COX,** individually and on behalf of all others similarly situated,

Plaintiffs,

vs.

**GRUMA CORPORATION,** *et al.*,

Defendant.

**Case No.: 12-CV-6502 YGR**

**ORDER GRANTING MOTION TO DISMISS IN PART (DKT. NO. 37) AND FOR REFERRAL TO THE UNITED STATES FOOD AND DRUG ADMINISTRATION**

Defendant Gruma Corporation filed its motion to dismiss (Dkt. No. 37) based upon primary jurisdiction, among other grounds. Plaintiff opposed the motion, and the Court considered the parties' arguments, as well as the parties' supplemental submissions (Dkt. Nos. 58, 64, and 67). Having carefully considered the submissions of the parties, the Court **GRANTS** the Motion, in part, on grounds of primary jurisdiction, as set forth herein.

Plaintiff brings this putative class action alleging that the labels on certain of Gruma Corporation's food products, as well as its advertising and marketing, are false and misleading in violation of the California Unfair Competition Law, Bus. & Prof. Code section 17200 *et seq*. ("UCL"); the California False Advertising Law, Cal. Bus. & Prof. Code section 17500 ("FAL"); the Consumers Legal Remedies Act, Cal. Civ. Code section 1750 *et seq*. ("CLRA"). Plaintiff alleges that, because Defendant's Products contain genetically modified organisms ("GMOs") in the form of corn grown from bioengineered, genetically modified seeds, Defendant's labels indicating the Products are "All Natural" are false and misleading. (Plaintiff's Amended Class Action Complaint [Dkt. No. 33, "FAC"] ¶¶ 39-43.)

"The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency… and is to be used only if a claim involves an issue of first impression or a particularly complicated issue Congress has committed to a regulatory agency." *Clark v. Time Warner Cable*, 523 F. 3d 1110, 1114 (9th Cir. 2008). A court traditionally weighs four factors in deciding whether to apply the primary jurisdiction doctrine: "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Syntek Semiconductor Co. v. Microchip Tech., Inc.,* 307 F.3d 775, 781 (9th Cir.2002) (amended).

The FDA has regulatory authority over food labeling. *See* 21 U.S.C. § 341 *et seq.* The Food, Drug, and Cosmetics Act (FDCA) establishes a uniform federal scheme of food regulation to ensure that food is labeled in a manner that does not mislead consumers. *See* 21 U.S.C. § 341 *et seq.* Food labeling enforcement is a matter that Congress has indicated requires the FDA's expertise and uniformity in administration. Congress amended the FDCA through the passage of the Nutrition Labeling and Education Act (NLEA) to "clarify and to strengthen" the FDA's "legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods." H.R. Rep. No. 101-538, at 7, *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337. No state may "directly or indirectly establish. . . any requirement for the labeling of food that is not *identical* to the [FDCA]." 21 U.S.C. § 343-1(a) (emphasis supplied).

Focusing particularly on the issues alleged in the FAC, there are no FDA rules requiring that products containing GMO or bioengineered ingredients be labeled as such. The FDA has issued nonbinding industry guidance indicating that it "is not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed . . . . FDA is therefore reaffirming its decision to not require special labeling of all bioengineered foods." (Defendant's Request for Judicial Notice, Exh. A ["Guidance for Industry: Voluntary Labeling Indicating

Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance," released for comment January 2001] at 2.) With respect to the use of the term "natural" on food labels, the agency has published non-binding guidance defining that term to mean that "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food." 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993). However, the parties appear to be in agreement that the FDA has not addressed, even informally, the question of whether foods containing GMO or bioengineered ingredients may be labeled "natural" or "all natural," or whether GMO or bioengineered ingredients would be considered "artificial or synthetic."

Thus, as Plaintiff concedes, "[t]he FAC identifies a gaping hole in the current regulatory landscape for 'natural' claims and GMOs, laying out how there is no direct regulation by the FDA of the term 'natural,' nor any requirement that a company disclose on a food product's label whether it contains GMOs." (Plaintiff's Memorandum of Points and Authorities in Opposition [Dkt. No. 47, "Oppo."] at 1:12-15, citing FAC at ¶¶ 20-25.) However, Plaintiff wrongly concludes that there is no agency charged with determining whether food labels may properly state that GMO products can be labeled "all natural." The FDCA and NLEA unquestionably and squarely give that authority to the FDA.

Under these circumstances, deference to the FDA's regulatory authority is the appropriate course. *Pom Wonderful, LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1176 (9th Cir. 2012); *Clark*, 523 F.3d at 1114. Otherwise, the Court would risk "usurp[ing] the FDA's interpretive authority[,]" and "undermining, through private litigation, the FDA's considered judgments." *Pom Wonderful*, 679 F.3d at 1176, 1178.

Therefore, the Court **ORDERS** as follows:

(1) pursuant to 21 C.F.R. § 10.25(c), this Court hereby **REFERS** to the FDA, for an administrative determination, the question of whether and under what circumstances food products containing ingredients produced using bioengineered seed may or may not be labeled "Natural" or "All Natural" or "100% Natural";

(2) this action is **STAYED** for a period of six (6) months from the date of this Order, which

period may be extended by further order of the Court upon a showing of good cause, including an indication from the FDA that it intends to resolve the issue;

(3) the parties and counsel will cooperate in expediting the presentation and explanation of this question to the FDA and will notify this Court promptly of any determination by the FDA;

(4) the request to except the parties pending discovery dispute from the stay is **DENIED** without prejudice to a showing of good cause why such dispute should be resolved by the Court during the pendency of the stay; and

(5) the Defendant's motion is **GRANTED** with respect to primary jurisdiction only, and is otherwise denied without prejudice to re-filing upon an order dissolving the stay ordered herein.

**IT IS SO ORDERED.** This Order terminates Docket No. 37.

**Date: July 11, 2013**

**YVONNE GONZALEZ ROGERS**
**UNITED STATES DISTRICT COURT JUDGE**

United States District Court
Northern District of California